Maine Organic Farmers and Gardeners Association

Common Ground Country Fair

September 15,2006

Arthur Neal
Director of Program Administration
National Organic Program
USDA-AMS-TMP-NOP
Room 4008 South Building
1400 Independence Ave., SW
Ag Stop 0268
Washington, D.C. 20250

Comments on Docket No. TM-03-04,
Submitted by email to national.list@usda.gov

Dear Mr. Neal:

Maine Organic Farmers and Gardeners Association would like to comment on the Proposed Amendments to the National List of Allowed and Prohibited Substances (Livestock). We would like to thank the NOP for moving forward to act upon the proposed recommendations that have been submitted by the National Organic Standards Board from November 15, 2000 to March 3, 2005 and we appreciate your taking public comment into consideration.

Primarily we are concerned about the substances that the NOSB recommended but the NOP did not propose:

- activated charcoal
- calcium borogluconate
- calcium propionate (for milk fever)
- kaolin pectin
- mineral oil
- propylene glycol

These materials are essential tools for dairy farmers to maintain the health of their cows. Many Jersey cows would no longer be alive without the ability of a farmer or veterinarian to administer either calcium borogluconate or calcium propionate for the treatment of parturient paresis ("milk fever"). Since cows in a recumbent stage of "milk fever" can quickly progress to loss of consciousness and coma, this condition is a true medical emergency. Intravenous administration of these calcium salts are simple remedies that quickly pass through an animal's system. Since no alternative treatment exists to calcium borogluconate, it is imperative, for health and welfare reasons, that their use is permitted on organic farms.

There are no documented residue problems in milk or meat from these materials. They are widely available and have been commonly used by conventional dairy producers as well as veterinarians with no noted impacts on the environment. All are allowed by FDA discretion and/or are low regulatory priority and can be marketed over the counter. The inclusion of aspirin on 7 CFR 205.603(a)(2) with the annotation 'approved for health care use to reduce inflammation' is a clear precedent that medications allowed by FDA discretion can be included on the National List. These substances have been demonstrated to be effective in restoring the health of animals. There was nothing to indicate in the petition, the TAP review, or any additional information submitted to the NOSB to suggest that the recommended substances were harmful to animal health, human health, or the environment.

The NOSB recognizes these substances to be consistent with organic farming and handling. In some cases nonsynthetic forms of these substances may be available (activated charcoal, kaolin pectin) and these forms should not be ruled out. Calcium borogluconate is used as an electrolyte, so it should not be considered prohibited as the preamble language suggests. We suggest that the substances listed above be placed on the National List as recommended by the NOSB, with the following restriction placed on each substance: "for use in organic production, unless subject to FDA regulatory discretion."

MOFGA recommends the addition of Moxidectin to the National List at 205.603((a)(19) Parasiticides. The NOSB recommended the addition of Moxidectin to the National List as a synthetic substance allowed for use in organic livestock production, including an identical annotation as that specified for Ivermectin. Moxidectin falls into the same classification of medication as Ivermectin. Moxidectin was not petitioned for use as an antibiotic. It is not licensed by the FDA for use as an antibiotic (TAP Review, Moxidectin, 2003 p.3). It was petitioned for use as a parasiticide, is legally registered for such use, and was recommended by the NOSB for such use. When the NOSB originally recommended Ivermectin, it did so recognizing that occasionally a producer may need a rescue treatment. The annotation is important so these parasiticides will not be permitted in slaughter stock, and so that use in dairy animals will carry an extended withhold time, both of which will eliminate the risk of residue in organic products. Ivermectin slow release formulations carry the risk of inhibiting activity of dung beetles and so the NOSB recommended an annotation prohibiting such formulations. We support the inclusion of this annotation. MOFGA supports the NOSB recommendation to list Moxidectin as an alternative parasiticide because it generates less toxicity for insects such as dung beetles and may be a tool needed as resistance to Ivermectin builds in common parasites.

MOFGA approves the materials that the NOP proposed to accept: atropine, bismuth subsalicylate, magnesium hydroxide, peracetic acid and excipients

The proposed amendment to the National List, does not accept the NOSB recommendation of double withholding time for Flunixin, Butorphonol and Furosemide, with the reasoning that such an annotation would create an additional and unacceptable label claim. Precedence for annotations that extend the FDA withholding time, exist in the current regulation. NOP agreed in 2000 to include extended withhold times for Ivermectin, lidocaine, and procaine in the Final Rule. Lidocaine is listed as a local anesthetic requiring "a withdrawal period of 90 days after administering to animals intended for slaughter and 7 days after administering to dairy animals." The FDA has not objected to this annotation, or similar restrictions on procaine and Ivermectin. The restriction suggested by the NOSB are based on information regarding drug

residues and withholding times that are derived from NADAs (new animal drug applications) as described in the USDA sponsored Food Animal Residue Avoidance Databank.

MOFGA suggests that the intent of the NOSB recommended withdrawal times can be maintained and reference to the FDA approved label can be avoided by using the following annotations:

- Flunixin – "For use in organic production, required withhold period of six days for dairy animals, and 42 days for slaughter stock."
- Butorphonol – "For use in organic production, required withhold period of eight days for dairy animals and 42 days for slaughter stock."
- Furosomide – "For use in organic production, required withhold of period of four days for both dairy animals and slaughter stock."

If ivermectin, lidocaine, and procaine have extended withdrawals with no objection by the NOP or FDA, then flunixin, furosemide, butorphanol, tolazoline, and xylazine should have extended withdrawals as well as recommended by the NOSB.

Additionally for the reasons mentioned above, we recommend that the following annotations be added to the proposed listings for the following substances:

- Poloxalene – "For use in organic production, only for the emergency treatment of bloat."
- Tolazoline – "For use in organic production as an emergency treatment, required withdrawal of four days for dairy animals and eight days for slaughter stock."
- Xylazine – "For use in organic production as an emergency treatment, required withdrawal of four days for dairy animals and eight days for slaughter stock.

One of the oldest and largest organic organizations in the country, MOFGA has 5,200 individual, family and business members and possesses extensive education, research and policy experience on a complete range of organic as well as non-organic farming and gardening issues. Our members, ranging from farmers to individual consumers to food retailers, care deeply about these issues and expect the organic label they see in the marketplace to reflect real needs of the farmers, regulators and consumers.

Sincerely,

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